

(A) Charge For The Human Health Risk Assessment Peer Review For The Rest Of The Housatonic River (6/1/2003)

<http://www.epa.gov/region1/ge/thesite/restofriver/reports/44312.pdf>

Under the Consent Decree, EPA is to conduct a Human Health Risk Assessment (HHRA) for the portion of the Housatonic River and its floodplain beginning at the confluence of the East and West Branches of the river (approximately two miles downstream of GE's facility in Pittsfield) and continuing downstream, excluding those portions of current residential properties in the floodplain that are or could be used as lawns (which are subject to separate remediation requirements under the Consent Decree). That stretch of the river and floodplain is known in the Consent Decree as the Rest of River. EPA has completed the HHRA for the Rest of River. The Consent Decree provides that the HHRA will be subject to Peer Review by a Peer Review Panel. This document provides the charge for the Peer Review of the HHRA for the Rest of River.

(B) Comments of Peer Reviewers for the Housatonic HHRA

PEER REVIEWERS (those with * addressed the breast milk pathway)

- Holly Hattemer-Frey*, ??????
- P. Barry Ryan*, Ph.D., Emory University
- Lee Shull PhD*, MWH Global
- Stephen T. Washburn*, ENVIRON International Corporation
- John C. Kissel, Ph.D, University of Washington
- Roger O. McClellan, DVM, DABT, DABVT, FATS Advisor: Toxicology and Human Health Risk Analysis
- F. Owen Hoffman, Ph.D, Senes Oak Ridge Inc, Center for Risk Analysis

QUESTIONS/RESPONSES THAT ADDRESSED BREASTMILK PATHWAY:

(1) Have the most important exposure pathways been identified and evaluated?

Peer Reviewer: Holly Hattemer-Frey

... All other complete exposure pathways were evaluated with the exception of the breast milk pathway. One reason given for not calculating potential exposures to infants from consumption of breast milk was lack of EPA guidance. However, methodologies for quantifying the breast milk pathway are available in EPA's (1988) Hazardous Waste Combustion Guidance. Unless EPA can provide new information as to why methodologies available in other EPA documents and the scientific literature are not appropriate, potential risks from consumption of breast milk should be quantified. While the contribution to overall risk from the breast milk pathway is likely to be small relative

to other pathways, risks for the breast milk pathway should be evaluated to verify their contribution to overall risk.....

Peer Reviewer: P. Barry Ryan, Ph.D., Emory University

...However, it would be useful to examine secondary pathways influenced by the direct contact pathway. Most notable among these is ingestion of breast milk from mothers exposed through this pathway. Since PCBs are lipophilic, storage in adipose tissues for a significant amount of time is possible. Washout of stored PCBs during pregnancy and lactation has been documented in many studies. It would be of interest to explore this pathway for relevance in the population living near the Housatonic that might give rise to this secondary pathway.

Peer Reviewer: Lee Shull PhD, MWH Global

.....The breast milk and transplacental pathways should be considered for inclusion in the residential population analysis. As was expressed at the public meeting November 18-20, potential health impacts associated with neonatal exposure to PCBs and dioxins/furans is among the greatest concerns of residents and medical personnel in the area. Risk assessment methods are available for such an analysis; EPA's *"Methodology for Assessing Health Risks Associated with Multiple Exposure Pathways to Combustor Emissions"* (2000?).....

PEER Reviewer: Stephen T. Washburn ENVIRON International Corporation

Overall, the most important exposure pathways have been identified and evaluated. As discussed above in the context of the Phase 1 screening for direct contact, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis.

(2) To the best of the Panel's knowledge, is there other pertinent information available that that was not considered in the HHRA? If so, please identify the studies or data that could have been considered, the relevance of such studies or data, and how they could have been used in the HHRA.

Peer Reviewer: Holly Hattemer-Frey

.....Potential risks to infants from consuming breast milk were not quantified. Guidance for performing this type of assessment can be found in the following references. I am sure other sources are available as well.

U.S. Environmental Protection Agency, *Guidance for Performing Screening Level Risk Analyses at Combustion Facilities Burning Hazardous Waste*, Office of Emergency and Remedial Response, Office of Solid Waste, April, October, and December, 1994.

Smith, A.H., 1987. Infant Exposure Assessment for Mother's Milk Dioxins and Furans Derived from Waste Incinerator Emissions, Risk Analysis, 7:347.....

(3) To the best of the Panel's knowledge, have relevant peer-reviewed studies that support, are directly relevant to, or fail to support any estimate of risk been identified and considered, and has an appropriate methodology been used to reconcile inconsistencies in the scientific data?

Peer Reviewer: Lee Shull PhD, MWH Global

... Another concern that was also mentioned in my comments is the failure of the HHRA to quantitatively address potential impacts associated with neonatal exposure (transplacental transfer of PCBs, breast milk pathway). The recent scientific literature on developmental effects in children (e.g., Schantz, 2003; Stewart et al., 2003) strongly supports the notion that EPA should assess neonatal risks associated with PCBs in the Housatonic River area. In addition to assessing theoretical neonatal health risks, I recommend that EPA consider a public health study consisting of sampling fetal blood and breast milk. These data, in addition to a risk assessment of neonates, would provide a basis for evaluating the potential impacts of PCBs in the area on neonates.....

(4) Were the procedures used in Phase 1 of the HHRA to screen out properties and areas from further evaluation as well as the application of those procedures appropriate under the evaluation criteria? In addressing this question, consider:

- **The general procedures used.**
- **The SRBCs used for the COPCs.**
- **The land use and exposure categories considered and the classification of particular parcels and areas into those categories.**

PEER Reviewer: Stephen T. Washburn ENVIRON International Corporation

.....The breast milk pathway should be further addressed for PCBs and dioxins/furans. I recognize that this pathway is often excluded from quantitative evaluation in risk assessments due to a lack of recent EPA guidance and limitations in available data. However, given the tendency for PCBs and dioxins/furans to accumulate in fat and both public and regulatory concerns regarding effects of short-term exposure on infants, I believe that the breast milk pathway should be included in an uncertainty analysis. A method for quantifying exposures through the breast milk pathway is described by Smith (1987) [*Infant Exposure Assessment for Mother's Milk Dioxins and Furans Derived from Waste Incinerator Emissions*, Risk Analysis, Volume 7]. This comment also applies to the Phase 2 direct contact, fish and waterfowl, and agricultural exposure evaluations.....

(5) Overall, was the approach used to assess risk from consumption of fish and waterfowl and other wild food items reasonable for evaluating the baseline risk?

PEER Reviewer: Stephen T. Washburn ENVIRON International Corporation

...As discussed above in the context of the direct contact scenarios, the breast milk pathway should be further addressed for PCBs and dioxins/furans in an uncertainty analysis for the fish and waterfowl consumption scenarios.....

(C) Responsiveness Summary to Public Comments On new Information HHRA for the GE/Housatonic River Site (Rest of River)

3. HIGHLY EXPOSED OR SUSCEPTIBLE SUBPOPULATIONS

SUMMARY OF ISSUE:

Six Reviewers pointed out that some potentially highly exposed or susceptible subpopulations were not evaluated in the risk assessment. Six Reviewers suggested that nursing infants, noted as the breast milk exposure pathway in the comments, be explicitly evaluated in the HHRA. One Reviewer recommended that children in the 1-6 year old age group evaluated in the HHRA be evaluated in shorter time spans, such as an age 2-3 year group. A second Reviewer supported this approach if a subchronic toxicity value for PCBs were available. Three Reviewers recommended the inclusion of a subsistence angler in the fish consumption pathway, at least at a screening level.

RESPONSE:

3.A. Nursing Infants (Breast Milk Pathway)

A new section will be included in the revised HHRA (Volume I) that evaluates exposure and risk to nursing infants. The methodology for this evaluation will be based on available guidance including the Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Volumes 1, 2 & 3, Peer Review Draft (EPA, 1998a) and Region VI Risk Management Addendum – Draft Human Health Risk Assessment Protocol for Hazardous Waste Combustion Facilities (EPA, 1998b).